REMARKS

Claims 1-26 were pending in this application. Claim 16 and 23-25 were withdrawn from examination as being directed to non-elected invention(s). Claims 23-26 have been canceled. Applicants reserve the right to pursue any canceled subject matter in one or more continuing applications. Rejections of canceled claims are hereafter treated as moot.

Claims 1, 2, 7, 9-11, 13-15, 17-20, and 22, and withdrawn claim 16 have been amended. Claims 9-11, 13-15, 18-20, and 22, and withdrawn claim 16 are amended to correct matters of form. Support for amending nucleotide residues in claims 1, 2, and 7 can be found, at least, in Figures 1A and 1B. Amended claim 17 is supported, for instance, by the combination of original claims 16 and 17, and by the specification, for instance, paragraphs [0036]-[0042] and, in particular, paragraph [0039].

New claims 27-30 have been added. Support for the new claims can be found, at least, in Figures 1A and 1B.

Eight paragraphs of the specification have been amended to correct obvious typographical errors and to formally demarcate trademarks with an appropriate symbol (™) indicating the proprietary nature of the mark.

No new matter is introduced by any of the foregoing amendments.

After entry of this Amendment, **claims 1-22 and 27-30 are pending in this application** (with claim 16 presently withdrawn from examination). Consideration of the pending claims is requested.

***Telephone Interview*:**

Applicants thank Examiner Collins for the courtesy of a telephone interview with their representatives, Debra A. Gordon and Tanya M. Harding, on August 18, 2006. During the telephone conference, the written description and enablement rejections were discussed. Applicants' representatives proposed amending claim 1 to recite a combination of particular

residues corresponding to TATA box and seed-specific elements in SEQ ID NO: 1 and its reverse complement and to cancel claim language directed to variants having 80% sequence identity. The Examiner stated that such an amended claim would more likely be considered by the Office to satisfy written description and enablement requirements.

Applicants' representatives and Examiner Collins discussed visual materials that might assist the Examiner in her examination of the claims and understanding of the application. Applicants provide herewith two exhibits, described in more detail below, to further this goal.

Complete agreement on claim amendments or arguments for overcoming the pending rejections was not reached; however, the Examiner provided helpful guidance and agreed to consider claim amendments and arguments filed by Applicants in a response to the Office action. It is believed that this Amendment conforms to the spirit of the telephone interview.

Attached Exhibits

To facilitate the Examiner's review of the amended claims and the arguments presented herein, Applicants provide in Exhibit A a version of Figures 1A and 1B to which has been added residue numbers and other labels for easy reference. Applicants also provide in Exhibit B a full-length version of the newly discovered promoter sequence in double-stranded format (top strand being SEQ ID NO: 1), and identify, for the Examiner's easy reference, the promoter elements described in the specification and as claimed.

Election/Restriction

As acknowledged by the Examiner, the claims of Group I and SEQ ID NO: 1 were elected in response to the Office action, dated November 3, 2005. The claims of elected Group I are directed to products. One or more process claims that depend from or otherwise include all of the limitations of an elected product claim are now withdrawn from examination (*e.g.*, claim 16). Applicants respectfully renew the request (made in the Amendment and Response to Restriction Requirement, submitted February 3, 2006) for rejoinder of such process claim, at the latest, upon the allowance of any of the elected product claims (in conformance with

MPEP §821.04 and Patent and Trademark Office Guidelines for Restriction Requirements in TC1600).

Claim Rejections under 35 U.S.C. §112, first paragraph

Claims 1-15, 17-22, and 26 have been rejected for, allegedly, failing to comply with the written description requirement of 35 U.S.C. §112, first paragraph. The Office Action contends that the claims "encompass numerous undisclosed and uncharacterized fragments or variants of SEQ ID NO: 1 and its reverse complement." Applicants traverse this rejection, at least, for reasons discussed below.

A statutorily adequate description of a claimed genus may be achieved by "sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus" (see, *e.g.*, MPEP §2163).

Applicants were in possession of the recited functional promoter fragments, at least, because the structure and function of numerous exemplary functional fragments (including, among others, nucleotides 1055-1127 of SEQ ID NO: 1, nucleotides 1168-1212 of SEQ ID NO: 1, nucleotides 854-918 of SEQ ID NO: 1, the reverse complement of nucleotides 142-214 of SEQ ID NO: 1, the reverse complement of nucleotides 58-101 of SEQ ID NO: 1, and the reverse complement of nucleotides 365-428 of SEQ ID NO: 1) are described in the specification. In addition, Applicants have described structural features that correspond to functional elements of the described promoters and have provided guidance on how such structural features can be modified to least likely affect function (see, *e.g.*, paragraphs [0020]-[0023] in combination with Figures 1A and 1B).

For instance, Applicants identified functional elements (*e.g.*, TATA box, and seed-specific element) in the newly discovered exemplary promoter by, among other things,

homology to known elements of similar function (see, *e.g.*, Example 1). Markedly, Applicants also showed that the exemplary promoter sequence (SEQ ID NO: 1) when aligned with its reverse complement (SEQ ID NO: 6) unexpectedly has three regions of surprisingly high sequence identity (see Figures 1A and 1B). Typically, such an alignment would not be expected to yield anything other than random nucleotide identities. Instead, Applicants have demonstrated a promoter sequence that is nearly palindromic with respect to three regions. Two such regions are those that include a TATA box and a seed-specific element, respectively (as discussed above). The third region is described as including an enhancer element (see, *e.g.*, paragraph [0023] of the specification).

The mismatched residues in the palindromic regions teach one of ordinary skill in the art at which positions variations likely can be tolerated. Similarly, one of ordinary skill in the art would easily appreciate that identical residues within a palindromic region likely could not be modified without affecting function of the corresponding element. Accordingly, Applicants have provided significant guidance as to structural features unique to a genus of variants and fragments of SEQ ID NO: 1 that have seed-associated promoter activity. In doing so, Applicants have demonstrated possession of such genus in satisfaction of the written description requirement.

Nevertheless, solely to facilitate prosecution of this application, Applicants have amended claims 1 and 2 to remove variants having 80% sequence identity to recited regions of SEQ ID NO: 1 and its reverse complement, and have canceled claim 26. Amended claim 1 recites particular residues of SEQ ID NO: 1 and its reverse complement, which by homology correspond to a TATA-box element and a seed-specific element, and which together predictably function as a seed-specific promoter as discussed above. Amended claim 2 recites particular residues of SEQ ID NO: 1 and its reverse complement that correspond to the third palindromic region, which is taught in the specification to be an enhancer element and, therefore, optional for seed-specific promoter activity.

Claims 3-15 and 17-22, each of which depend (directly or indirectly) from claim 1 are believed to satisfy the written description requirement for the same reasons as discussed for claim 1.

In view of the foregoing arguments and claim amendments, Applicants request that this rejection be withdrawn.

Claims 1-15, 17-22, and 26 have been rejected, allegedly, for failing to comply with the enablement requirement of 35 U.S.C. §112, first paragraph. In particular, the Office contends that "it is unpredictable whether fragments or sequence variants of SEQ ID NO: 1 or its reverse complement would function as a promoter, or as a seed-associated promoter, because basal and tissue-specific promoter function requires the presence of specific nucleotides and nucleotide sequence motifs in a particular arrangement." Applicants traverse this rejection at least for the reasons discussed below.

"The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation" (see MPEP § 2164.01 citing *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) and *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). It is also accepted in U.S. patent law that a "patent [application] need not teach, and preferably omits, what is well known in the art" (see MPEP § 2164.01 citing numerous Federal Circuit cases).

The "test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed" (MPEP §2164.06 citing *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). Some of the factors to be considered in determining whether experimentation is "undue" for purposes of enablement, "include, but are not limited to: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount

of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure" (MPEP §2164.01(a) citing *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)).

In the present case, the skill in the art of molecular biology is high and the making of sequence variants and fragments of a disclosed nucleic acid sequence is, and has been for some time, routine in this art (see, *e.g.*, Sambrook *et al.*, *Molecular Cloning: A Laboratory Manual*, Cold Spring Harbor, New York:Cold Spring Harbor Press, 1989 ("Sambrook"), and Ausubel *et al.*, *Current Protocols in Molecular Biology*, Greene Publ. Assoc. and Wiley-Intersciences, 1998). More particularly, promoter mapping is, and was at the time of filing the present application, standard practice; as evidenced, for example, by the references cited by the examiner (*e.g.*, "[s]tandard cloning, construction and sequencing techniques were performed following the guidelines given in Sambrook" at page 670, column 1, Fiedler *et al.*, *Plant Mol. Biol.*, 22:669-679, 1993). Additionally, Applicants have provided, at least, (i) a full-length promoter sequence to be mapped, which is a main obstacle to promoter mapping, (ii) the location of known functional elements (*e.g.*, a TATA box, and "a legumin box," which has been shown to direct seed-specific expression) within the full-length sequence; and, as described in detail above, (iii) a specification that teaches a person of ordinary skill in the art at which positions variations likely can or likely can not be made in SEQ ID NO: 1 and its reverse complement to produce a genus of sequence variants and fragments having seed-associate promoter activity.

With the foregoing information in hand, it would be a routine matter using now-standard molecular techniques for a person of ordinary skill in the art to make sequence variants of the disclosed promoter sequence and to use such sequence variants as also described in detail in the specification. Nevertheless, to facilitate prosecution of this application, Applicants have amended the rejected claims to remove reference to sequence variants. Thus, this aspect of the rejection has been rendered moot.

With respect to recited fragments of SEQ ID NO: 1 and its reverse complement, it is believed the Office does not dispute that one of ordinary skill in the art readily could make

fragments of SEQ ID NO: 1 and its reverse complement with out undue experimentation. The issue appears to be whether identifying functional fragments (*i.e.*, fragments having seed-associated promoter activity) among the fragments that could be made would amount to undue experimentation.

Applicants respectfully submit that, even without further guidance provided by Applicants' specification (as discussed below), there are a finite number of fragments of SEQ ID NO: 1 and its reverse complement, and only a few of those need be examined for seed-associated expression to quickly hone in on fragments having the function of interest. Each fragment (whether functional or non-functional) would direct a person of ordinary skill in the art to the functional fragments of interest. It would not be necessary to test every fragment imaginable or even a significant number of same. Thus, given only an exemplary promoter sequence (such as SEQ ID NO: 1 or its reverse complement), a function of such promoter (such as seed-associated expression), and a representative method to test such function (such as provided in Example 3 of the specification), routine experimentation would identify fragments of such sequence having the stated function.

Nevertheless, as discussed in detail above, the present specification teaches the locations of particular functional elements, *e.g.*, TATA box and seed-specific element, which are features of the recited promoter sequence, and teaches where sequence modifications likely will or will not affect seed-associated promoter function. Thus, one of ordinary skill in the art could make or use the promoter recited in the rejected claims (particularly as amended) from the disclosure in the patent application coupled with information known in the art without undue experimentation, which satisfies the enablement requirement.

In view of the foregoing arguments and the amendments to claim 1 and its dependent claims, Applicants request that this rejection be withdrawn.

Claim Rejection under 35 U.S.C. §112, second paragraph

Claim 26 has been rejected under 35 U.S.C. §112, second paragraph, allegedly, as being indefinite in its recitation of "high stringency conditions." Applicants traverse this rejection, at

least, because "[d]efiniteness of claim language must be analyzed [by the Office], not in a vacuum, but in light of . . . [t]he content of the particular application disclosure . . . " (MPEP 2173.02). Exemplary high stringency conditions for hybridization are clearly provided in the specification (see, *e.g.*, paragraph [0024]); therefore, "the public is informed of the boundaries of [claim 26]," which is the "primary purpose of [the 35 U.S.C. §112, second paragraph] requirement of definiteness of claim language" (MPEP 2173).

Nevertheless, solely to facilitate prosecution of this application, claim 26 has been canceled. Thus, this rejection of claim 26 is moot and Applicants respectfully request that the rejection be withdrawn.

CONCLUSION

It is respectfully submitted that the present claims are in a condition for allowance. If any issues remain, the Examiner is requested to contact the undersigned prior to issuance of the next Office action in order to arrange a telephone interview. It is believed that a brief discussion of the merits of the present application may expedite prosecution and allowance of the claims.

Respectfully submitted,

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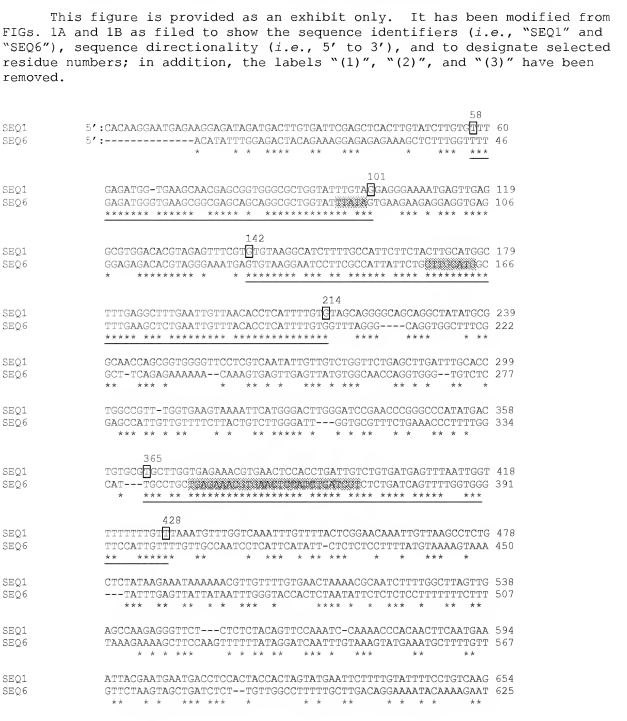
EXHIBIT A

FIGs. 1A and 1B
SEQ ID NO: 1 ALIGNED TO ITS REVERSE COMPLEMENT (SEQ ID NO: 6)

This figure is provided as an exhibit only. It has been modified from FIGs. 1A and 1B as filed to show the sequence identifiers (*i.e.*, "SEQ1" and "SEQ6"), sequence directionality (*i.e.*, 5′ to 3′), and to designate selected residue numbers; in addition, the labels "(1)", "(2)", and "(3)" have been removed.



```
SEQ1      AATTGATCCTATAAAAAACTTGGAAGCTTTTCTTTAAAAGAAAAAAAGGAGAGAGAATAT 772
SEQ6      ATTTGGAACTGTAGAGAG---AGAACCCTCTTGGCTCAACTAAGCCAAAAGATTGCGTTT 741
          * ***   ** ** * *      *** * * *        **  **    *  ***  *  * *

SEQ1      TAGAGTGGTACCCAAATTATAATAACTCAAATA---TTTACTTTTACATAAAAGGAGAGA 829
SEQ6      TAGTTCACAAAACAACGTTTTTTATTTCTTATAGAGCAGAGGCTTAACAATTTGTTCCGA 801
          ***       *  ***  * *  **  **  ***        *   ***   *   *    **

                                        854
SEQ1      G-AATATGAATGAGGATTGGCAACAAAACAATGGAACCCACCAAAACTGATCAGAGACGA 888
SEQ6      GTAAAACAAATTTGACCAAACATTTAAACAAAAAAAACCAATTAAACTCATCACAGACAA 861
          * ** *  ***  *        **  ******    ** ***    ***** **** **** *

                                             918
SEQ1      TCAGATGGAGTTCACGTTTCTCAGCAGGCA---ATGCCAAAAGGGTTTCAGAAACGCACC 945
SEQ6      TCAGGTGGAGTTCACGTTTCTCACCAAGCACGCACAGTCATATGGGCCCGGGTTCGGATC 921
          **** ***************** ** ***    *      * * **    * *    ** * *

SEQ1      ---AATCCCAAGACAGTAAGAAAACAACAATGGCTCGAGACA--CCCACCTGGTTGCCAC 1000
SEQ6      CCAAGTCCCATGAATTTTACTTCACCA-AACGGCCAGGTGCAAATCAAGCTCAGAACCAG 980
             * ***** **    * *     ** * ** ***  *    **    * * **      ***

SEQ1      ATAACTCAACTCACTTTG--TTTTTTCTCTGAA-GCCGAAAGCCACCTGC----CCTAAA 1053
SEQ6      ACAACAATATTGACGAGGAACCCCACCGCTGGTTGCCGCATATAGCCTGCTGCCCCTGCT 1040
          * ***    * * **    *          * ***   **** *      *****     ***

           1055
SEQ1      CCACAAAATGAGGTGTAAACAATTCAGAGCTTCAAAGCCATGCAAGCAGAATAATGGCGA 1113
SEQ6      ACACAAAATGAGGTGTTAACAATTCAAAGCCTCAAAGCCATGCAAGTAGAAGAATGGCAA 1100
           *************** ********* *** *************** **** ****** *

                       1127                                       1168
SEQ1      AGGATTCCTTACACTCATTTCCCTACGTGTCTCTCCCTCACCTCCTCTTCTTCACTATAA 1173
SEQ6      AAGATGCCTTACACACGAAACTCTACGTGTCCACGCCTCAACTCATTTTCCCTCCTACAA 1160
          * *** ******** *     * *********     ***** *** * ***      *** **

                                                 1212
SEQ1      ATACCAGCGCCTGCTGCTCGCCGCTTCACCCATCTCAAAACCAAAGAGCTTTCTCTCTCC 1233
SEQ6      ATACCAGCGCCCACCGCTCGTTGCTTCACC-ATCTCAAACACAAGATACAAGTGAGCTCG 1219
          ***********  * *****  ******** ********  ***     *        ***

SEQ1      TTTCTGTAGTCTCCAAATATGT-------------- 1255
SEQ6      AATCACAAGTCATCTATCTCCTTCTCATTCCTTGTG 1255
```

EXHIBIT B

Bi-Directional Promoter
(SEQ ID NO: 1 shown double stranded)

```
5'-cacaaggaatgagaaggagatagatgacttgtgattcgagctcacttgtatcttgtgtttgagatggtgaa      71
3'-GTGTTCCTTACTCTTCCTCTATCTACTGAACACTAAGCTCGAGTGAACATAGAACACAAACTCTACCACTT
                                                              58

gcaacgagcggtgggcgctggtatttgtaggagggaaaatgagttgaggcgtggacacgtagagtttcgtg      142
CGTTGCTCGCCACCCGCGACCATAAACATCGTCCCTTTTACTCAACTCCGCACCTGTGCATCTCAAAGCAC
Bottom-strand TATA Element     101                                    142

tgtaaggcatcttttgccattcttctacttgcatggctttgaggctttgaattgttaacacctcattttgt      213
ACATTCCGTAGAAAACGGTAAGAAGATGAACGTACGAAACTCCGAAACTTAACAATTGTGGAGTAAAACA
                    Bottom-strand Seed-specific Element

gtagcaggggcagcaggctatatgcggcaaccagcggtgggttcctcgtcaatattgttgtctggttctg      284
CATCGTCCCCGTCGTCCGATATACGCCGTTGGTCGCCACCCCAAGGAGCAGTTATAACAACAGACCAAGAC
214

agcttgatttgcacctggccgtttggtgaagtaaaattcatgggacttgggatccgaacccgggcccatat      355
TCGAACTAAACGTGGACCGGCAAACCACTTCATTTTAAGTACCCTGAACCCTAGGCTTGGGCCCGGGTATA

gactgtgcgtgcttggtgagaaacgtgaactccacctgattgtctgtgatgagtttaattggtttttttg      426
CTGACACGCACGAACCACTCTTTGCACTTGAGGTGGACTAACAGACACTACTCAAATTAACCAAAAAAAC
          365                Bottom-strand Enhancer

tttaaatgtttggtcaaatttgttttactcggaacaaattgttaagcctctgctctataagaaataaaaaa      497
AAATTTACAAACCAGTTTAAACAAAATGAGCCTTGTTTAACAATTCGGAGACGAGATATTCTTTATTTTTT
 428

cgttgttttgtgaactaaaacgcaatcttttggcttagttgagccaagagggttctctctctacagttcca      568
GCAACAAAACACTTGATTTTGCGTTAGAAAACCGAATCAACTCGGTTCTCCCAAGAGAGAGATGTCAAGGT

aatccaaaacccacaacttcaatgaaattacgaatgaatgacctccactaccactagtatgaattcttttg      639
TTAGGTTTTGGGTGTTGAAGTTACTTTAATGCTTACTTACTGGAGGTGATGGTGATCATACTTAAGAAAAC

tattttcctgtcaagcaaaaaggccaacaagagatcagctacttagaacaacaaaagcatttcatacttta      710
ATAAAAGGACAGTTCGTTTTTCCGGTTGTTCTCTAGTCGATGAATCTTGTTGTTTTCGTAAAGTATGAAAT

caaattgatcctataaaaaacttggaagcttttcttaaaagaaaaaaaggagagaatattagagtggt      781
GTTTAACTAGGATATTTTTTGAACCTTCGAAAAGAAATTTTCTTTTTTTCCTCTCTCTTATAATCTCACCA

acccaaattataataactcaaatatttacttttacatagaaaggagagagaatatgaatgaggattggcaac      852
TGGGTTTAATATTATTGAGTTTATAAATGAAAATGTATTTTCCTCTCTCTTATACTTACTCCTAACCGTTG

 854                    Top-strand Enhancer                        918
aaaacaatggaacccaccaaaactgatcagagacgatcagatggagttcacgtttctcagcaggcaatgcc      923
TTTTGTTACCTTGGGTGGTTTTGACTAGTCTCTGCTAGTCTACCTCAAGTGCAAAGAGTCGTCCGTTACGG

aaaaggtttcagaaacgcaccaatcccaagacagtaagaaaacaacaatggctcgagacacccacctggt      994
TTTTCCCAAAGTCTTTGCGTGGTTAGGGTTCTGTCATTCTTTTGTTGTTACCGAGCTCTGTGGGTGGACCA
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1055

tgccacataactcaactcactttgtttttttctctgaagccgaaagccacctgccctaaaccacaaaatgag 1065
ACGGTGTATTGAGTTGAGTGAAACAAAAAAGAGACTTCGGCTTTCGGTGGACGGGATTTGGTGTTTTACTC

Top-strand Seed-specific Element 1127

gtgtaaacaattcagagcttcaaagcgtgcaagcagaataatggcgaaggattccttacactcatttccc 1136
CACATTTGTTAAGTCTCGAAGTTTCGGTACGTTCGTCTTATTACCGCTTCCTAAGGAATGTGAGTAAAGGG

1168 Top-strand TATA Element

tacgtgtctctccctcacctcctcttcttcactataaataccagcgcctgctgctcgccgcttcacccatc 1207
ATGCACAGAGAGGGAGTGGAGGAGAAGAAGTGATATTTATGGTCGCGGACGACGAGCGGCGAAGTGGGTAG

1212

tcaaaaccaaagagctttctctctcctttctgtagtctccaaatatgt-3′ (SEQ ID NO: 1) 1255
AGTTTTGGTTTCTCGAAAGAGAGAGGAAAGACATCAGAGGTTTATACA-5′